

**REMARKS**

Entry of this Amendment is proper under 37 C.F.R. § 1.116 because the Amendment places the application in condition for allowance for the reasons discussed herein; and does not raise any new issues requiring further search and/or consideration. Entry of the Amendment is thus respectfully requested.

As stated in the Office Action Summary, claims 7-21, 23-28 and 30-35 are currently pending. Claims 18-19 stand withdrawn. Claims 7 and 20 are amended herein to recite that the tissue factor or fragment thereof is administered in the form of an expressible nucleic acid present in a plasmid vector. Basis for these amendments may be found throughout the specification and claims as-filed, especially at the Example on pages 6-8 of the specification (disclosing the preparation of a tissue factor-expressing plasmid and the use of same in influencing blood vessel formation). Thus, no new matter is presented by way of the present Amendment.

Claims 11, 18-20, 23-27 and 33-35 are canceled herein. Applicants reserve the right to file at least one continuation or divisional application directed to any subject matter canceled by way of the present Amendment.

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 7-17, 20, 21, 23-28 and 30-35 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for activating blood vessel formation or enhancing wound healing in a subject in need comprising administering a nucleic acid expressing the Tissue Factor (TF) locally, wherein the nucleic acid is a plasmid vector comprising a constitutive promoter, is purportedly not

enabling for the activation of blood vessel formation or the enhancement of wound healing in a subject in need comprising inducing local expression of a TF by any means or locally administering any type of nucleic acid comprising an inducible promoter operably linked to a TF.

Without acquiescing in this rejection, and in the interest of expediting prosecution, Application have amended independent claims 7 and 20 herein to recite subject matter which the Examiner states is enabled, *i.e.*, blood vessel formation or enhancing wound healing in a subject in need comprising administering a nucleic acid, wherein the nucleic acid is a plasmid vector.

With regard to the induction of local expression of the Tissue Factor nucleic acid, in light of the amendments to the claims made herein, Applicants submit that "inducible promoter" is enabled. First, the independent claims are amended herein to recite a nucleic acid in the form of a plasmid vector. Thus, the dependent claims are also directed to plasmid vectors. The reference cited by the Examiner to support the argument that the claims lack enablement, Miller et al., is directed solely to viral vectors. In fact, in the Office Action of June 18, 2003, the Examiner emphasizes that Miller et al. concerns viral vectors (see Office Action mail dated June 18, 2003, page 7). Therefore, the reference is not relevant to the claims as amended herein.

Finally, on page 4 of the present Office Action, the Examiner states that the term "modulating blood vessel formation" as recited in the claims may encompass both activation and reduction of blood vessel formation. Applicants submit that the claims recite the element "wherein the modulating is an activation of blood vessel formation", and therefore, the modulation recited in the claims is clearly the activation of blood vessel formation and not the reduction of blood vessel formation.

However, in the interest of expediting prosecution, claim 7 is amended herein to recite activation of blood vessel formation in the preamble as well as in the body of the claim.

In light of the above remarks, and claim amendments set forth herein, Applicants request that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

**CONCLUSION**

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.


In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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By:



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